

Copy



Patent
Attorney's Docket No. 028723-060

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)
Joe W. GRAY et al)
Application No.: 08/477,316) Group Art Unit: 1807
Filed: June 7, 1995) Examiner: Unassigned
For: CHROMOSOME-SPECIFIC)
STAINING TO DETECT)
GENETIC REARRANGEMENTS)

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. §1.56, Applicants hereby submit the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98. Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited was submitted in Application No. 08/487,701 upon which is based a claim for priority under 35 U.S.C. §120.

U.S. PATENTS

4,888,278
4,772,691
4,770,992
4,725,536
4,721,669
4,711,955
4,710,465
4,707,440
4,683,195
4,681,840
4,647,529
4,358,535

FOREIGN PATENTS

2019408	UK
2215724	UK
8705027	WO
9005789	WO

OTHER DOCUMENTS

Albertson, "Mapping Muscle Protein Genes by *in situ* Hybridization Using Biotin-Labeled Probes," EMBO J., Vol. 4, No. 10, 1985, pp. 2493-2498

Albertson, "Localization of the Ribosomal Genes in *Caenorhabditis elegans* Chromosomes by *in situ* Hybridization Using Biotin-Labeled Probes," EMBO J., Vol. 3, No. 6, 1984, pp. 1227-1234

Ardeshir et al, "Structure of Amplified DNA in Different Syrian Hamster Cell Lines Resistant to *N*-(Phosphonacetyl)-L-Aspartate," Molecular and Cellular Biology, Vol. 3, No. 11, Nov. 1983, pp. 2076-2088

Arnoldus et al, "Detection of the Philadelphia Chromosome in Interphase Nuclei (With 2 Color Plates)," Cytogenet. Cell Genet., Vol. 54, 1990, pp. 108-111

Bar-Am et al, "Detection of Amplified DNA Sequences in Human Tumor Cell Lines by Fluorescence In Situ Hybridization," Genes, Chromosomes & Cancer, Vol. 4, 1992, pp. 314-320

Benton et al, "Screening λgt Recombinant Clones by Hybridization to Single Plaques *in situ*," Science, Vol. 196, 1977, pp. 180-182

Bergerheim et al, "Deletion Mapping in Human Renal Cell Carcinoma," Cancer Res., Vol. 49, March 1989, pp. 1390-1396

Bookstein et al, "Human Retinoblastoma Susceptibility Gene: Genomic Organization and Analysis of Heterozygous Intragenic Deletion Mutants," PNAS (USA), Vol. 85, April 1988, pp. 2210-2214

Brison et al, "General Method for Cloning Amplified DNA by Differential Screening with Genomic Probes," Molecular and Cellular Biology, Vol. 2, No. 5, May 1982, pp. 578-587

Britten et al, "Analysis of Repeating DNA Sequences by Reassociation," Methods of Enzymology, Vol. 29, 1974, pp. 363-418

Buongiorno-Nardelli et al, "Autoradiographic Detection of Molecular Hybrids between rRNA and DNA in Tissue Sections," NATURE, Vol. 225, March 1970, pp. 946-948

Cannizzaro et al, "In Situ Hybridization and Translocation Breakpoint Mapping II. Two Unusual t(21;22) Translocations," Cytogenet. Cell Genet., Vol. 39, 1985, pp. 173-178

Cantor et al, "The Behavior of Biological Macromolecules, Part III," Biophysical Chemistry, Freeman & Co. 1980, pp. 1183, 1226-1228

Cohen et al, "Hereditary Renal-Cell Carcinoma Associated with a Chromosomal Translocation," N. Engl. J. Med., Vol. 301, No. 11, Sept. 1979, pp. 592-595

Collins and Weissman, "Directional cloning of DNA fragments at a large distance from an initial probe: A circularization method", PNAS (USA), 81: 6812-6816 (November 1984)

Cox et al, "Detection of mRNAs in Sea Urchin Embryos by *in Situ* Hybridization Using Asymmetric RNA Probes," Developmental Biology, Vol. 101, 1984, pp. 485-502

Cremer et al, "Detection of Chromosome Aberrations in Metaphase and Interphase Tumor Cells by *in situ* Hybridization Using Chromosome-Specific Library Probes," Human Genetics, Vol. 80, 1988, pp. 235-246

Cremer et al, "Detection of Chromosome Aberrations in the Human Interphase Nucleus by Visualization of Specific Target DNAs with Radioactive and Non-Radioactive *in situ* Hybridization Techniques: Diagnosis of Trisomy 18 with Probe L1.84," Hum. Genet., Vol. 74, 1986, pp. 346-352

Cremer et al, "Rapid Interphase and Metaphase Assessment of Specific Chromosomal Changes in Neuroectodermal Tumor Cells by *in Situ* Hybridization with Chemically Modified DNA Probes," Exp. Cell Res., Vol. 176, 1988, pp. 199-220

Cremer et al, "Rapid Metaphase and Interphase Detection of Radiation-Induced Chromosome Aberrations in Human Lymphocytes by Chromosomal Suppression In Situ Hybridization," Cytometry, Vol. 11, 1990, pp. 110-118

Devilee et al, "Detection of Chromosome Aneuploidy in Interphase Nuclei from Human Primary Breast Tumors Using Chromosome-specific Repetitive DNA Probes," Cancer Res., Vol. 48, Oct. 1988, pp. 5825-5830

Durnam et al, "Detection of Species Specific Chromosomes in Somatic Cell Hybrids," Som. Cell Molec. Genetics, Vol. 11, No. 6, 1985, pp. 571-577

Erikson et al, "Heterogeneity of Chromosome 22 Breakpoint in Philadelphia-positive (Ph⁺) Acute Lymphocytic Leukemia," PNAS, USA, Vol. 83, March 1986, pp. 1807-1811

Fisher et al, "Adhesive and Degradative Properties of Human Placental Cytotrophoblast Cells In Vitro," J. Cell Biol., Vol. 109, No. 2, 1989, pp. 891-902

Fisher et al, "Molecular Hybridization Under Conditions of High Stringency Permits Cloned DNA Segments Containing Reiterated DNA Sequences to be Assigned to Specific Chromosomal Locations," PNAS, USA, Vol. 81, Jan. 1984, pp. 520-524

Friend et al, "A Human DNA Segment with Properties of the Gene that Predisposes to Retinoblastoma and Osteosarcoma," Nature, Vol. 323, Oct. 16, 1986, pp. 643-646

Fuscoe et al, "An Efficient Method for Selecting Unique-Sequence Clones from DNA Libraries and Its Application To Fluorescent Staining of Human Chromosome 21 Using *in Situ* Hybridization," Genomics, Vol. 5, 1989, pp. 100-109

Gall et al, "Formation and Detection of RNA-DNA Hybrid Molecules in Cytological Preparations," PNAS (USA), Vol. 63, 1969, pp. 378-383

Gray et al, "Flow Cytometric Detection of Chromosome Aberrations," (Abstract) Conference on Flow Cytometry in Cell Biology and Genetics, Clift Hotel, San Francisco, California, 1/15/85 -1/17/85

Gray et al, "Fluorescence Hybridization to Human Chromosome 21 Using Probes From A Charon 21 A Library," Cytometry, (Suppl. 1), 1987, Abst. 19, pg. 4

Grunstein et al, "Colony Hybridization: A Method for the Isolation of Cloned DNAs That Contain A Specific Gene," PNAS, USA, Vol. 72, No. 10, Oct. 1975, pp. 3961-3965

Harper et al, "Localization of Single Copy DNA Sequences on G-Banded Human Chromosomes by *in situ* Hybridization," Chromosoma (Berl.), Vol. 83, 1981, pp. 431-439

Harper et al, "Localization of the Human Insulin Gene to the Distal End of the Short Arm of Chromosome 11," PNAS (USA), Vol. 78, No. 7, July 1981, pp. 4458-4460

Herzenberg et al, "Fetal Cells in the Blood of Pregnant Women: Detection and Enrichment by Fluorescence-Activated Cell Sorting," PNAS (USA), Vol. 76, No. 3, March 1979, pp. 1453-1455

Leroy E. Hood et al, Molecular Biology of Eucaryotic Cells, W. A. Benjamin, Inc., Menlo Park, CA, pgs. 47-51 (1975)

Jabs et al, "Characterization of a Cloned DNA Sequence that is Present at Centromeres of All Human Autosomes and the X Chromosome and Shows Polymorphic Variation," PNAS (USA), Vol. 81, August 1984, pp. 4884-4888

John et al, "RNA-DNA Hybrids at the Cytological Level," NATURE, Vol. 223, August 1969, pp. 582-587

Kao et al, "Assignment of the Structural Gene Coding for Albumin to Human Chromosome 4," Human Genetics, Vol. 62, 1982, pp. 337-341

Kievits et al, "Direct Nonradioactive In Situ Hybridization of Somatic Cell Hybrid DNA to Human Lymphocyte Chromosomes," Cytometry, Vol. 11, 1990, pp. 105-109

Landegent et al, "Use of Whole Cosmid Cloned Genomic Sequences for Chromosomal Localization of Non-Radioactive *in situ* Hybridization," Hum. Genet., Vol. 77, 1987, pp. 366-370

Landegent et al, "Chromosomal Localization of a Unique Gene by Non-Autoradiographic *in situ* Hybridization," Nature, Vol. 317, Sept. 1985, pp. 175-177

Landegent et al, "2-Acetylaminofluorene-Modified Probes for the Indirect Hybridocytological Detection of Specific Nucleic Acid Sequences," Exp. Cell Res., Vol. 153, 1984, pp. 61-72

Landegren et al, "DNA Diagnostics -- Molecular Techniques and Automation," Science, Vol. 242, Oct. 1988, pp. 229-237

Langer-Safer et al, "Immunological Method for Mapping Genes on *Drosophila* Polytene Chromosomes," PNAS (USA), Vol. 79, 1982, pp. 4381-4385

Lawrence et al, "Sensitive, High-Resolution Chromatin and Chromosome Mapping *In Situ*: Presence and Orientation of Two Closely Integrated Copies of EBV in a Lymphoma Line," Cell, Vol. 52, Jan. 1988, pp. 51-61

LeGrys et al, "Clinical Applications of DNA Probes in the Diagnosis of Genetic Diseases," CRC Crit. Rev. Clin. Lab. Sci., Vol. 25, No. 4, 1987, pp. 255-274

Lewin, "Genetic Probes Become Ever Sharper - Rapid Detection of Multiple-Pathogen Infections, Including Major Drug-Resistance Genes, May be Possible Using a Newly Developed Technique," Science, Vol. 221, No. 4616, Sept. 1983, p. 1167

Lewin, Genes, (2nd Ed., John Wiley & Sons, Inc. 1984) pp. 298-299 and pp. 464-465

Lichter et al, "Delineation of Individual Human Chromosomes in Metaphase and Interphase Cells by *in situ* Suppression Hybridization Using Recombinant DNA Libraries," Human Genet., Vol. 80, 1988, pp. 224-234

Lichter et al, "Rapid Detection of Human Chromosome 21 Aberrations by *in situ* Hybridization," PNAS USA, Vol. 85, Dec. 1988, pp. 9664-9668

Lichter et al, "High-Resolution Mapping of Human Chromosome 11 by *in Situ* Hybridization with Cosmid Clones," Science, Vol. 247, Jan. 5, 1990, pp. 64-69

Lichter et al, "Is Non-Isotopic *in situ* Hybridization Finally Coming of Age?," Nature, Vol. 345, May 1990, pp. 93-94

Litt et al, "A Highly Polymorphic Locus in Human DNA Revealed by Cosmid-Derived Probes," PNAS, USA, Vol. 82, Sept. 1985, pp. 6206-6210

LLNL, "Fluorescent Labeling of Human Chromosomes with Recombinant DNA Probes," Energy & Tech. Review, July 1985, pp. 84-85

LLNL, "Chromosome-Specific Human Gene Libraries, Energy & Tech. Review, July 1985, pp. 82-83

Lucas et al, "Rapid Translocation Analysis Using Fluorescence *In Situ* Hybridization: Applied to Long Term Biological Dosimetry", (UCRL 102265 Abstract), Radiation Research Meeting, New Orleans, Louisiana, 4/7/90 - 4/12/90

Manuelidis, "Individual Interphase Chromosome Domains Revealed by *in situ* Hybridization," Hum. Genet., Vol. 71, 1985, pp. 288-293

Manuelidis et al, "Chromosomal and Nuclear Distribution of the HindIII 1.9-kb Human DNA Repeat Segment," Chromosoma (Berl.), Vol. 91, 1984, pp. 28-38

Manuelidis, "Different Central Nervous System Cell Types Display Distinct and Nonrandom Arrangements of Satellite DNA Sequences," PNAS (USA), Vol. 81, May 1984, pp. 3123-3127

McCormick, "The Polymerase Chain Reaction and Cancer Diagnosis," Cancer Cells, Vol. 1, No. 2, Oct. 1989, pp. 56-61

Montgomery et al, "Specific DNA Sequence Amplification in Human Neuroblastoma Cells," PNAS USA, Vol. 80, Sept. 1983, pp. 5724-5728

Nederlof et al, "Detection of Chromosome Aberrations in Interphase Tumor Nuclei by Nonradioactive *In Situ* Hybridization," Cancer Genet. Cytogenet., Vol. 42, 1989, pp. 87-98

Olsen et al, "Isolation of Unique Sequence Human X Chromosomal Deoxyribonucleic Acid," Biochemistry, Vol. 19, 1980, pp. 2419-2428

Pinkel et al, "Detection of Structural Chromosome Aberrations in Metaphase Spreads and Interphase Nuclei by *in situ* Hybridization High Complexity Probes Which Stain Entire Human Chromosomes," Am. J. Hum. Genet. (Supplement) Vol. 43, No. 3, Sept. 1988, p. A118 (Abstract 0471: 11.5)

Pinkel et al, "Cytogenetic Analysis Using Quantitative, High-Sensitivity, Fluorescence Hybridization," PNAS (USA), Vol. 83, May 1986, pp. 2934-2938

Pinkel et al, "Cytogenetic Analysis by *In Situ* Hybridization with Fluorescently Labeled Nucleic Acid Probes," Cold Spring Harbor Symposia on Quantitative Biology, Vol. LI, 1986, pp. 151-157

Pinkel et al, "Genetic Analysis by Quantitative Microscopy and Flow Cytometry Using Fluorescence *In Situ* Hybridization with Chromosome-Specific Nucleic Acid Probes," Am. J. Hum. Genet. (Supplement), Vol. 39, No. 3, Sept. 1986, p. A129 (379)

Pinkel et al, "Cytogenetic Analysis During Leukemia Therapy Using Fluorescence *in situ* Hybridization with Chromosome-Specific Nucleic Acid Probes," Am. J. Hum. Genet. (Supplement), Vol. 41, No. 3, Sept. 1987, p. A34 (096; 12.12)

Pinkel et al, "Simplified Cytogenetics Using Biotin Labeled Nucleic Acid Probes and Quantitative Fluorescence Microscopy," Am. J. Hum. Genet. (Supplement), Vol. 37, No. 4, July 1985, pp. A112 (328; 17.2)

Pinkel et al, "Fluorescence *in situ* Hybridization with Human Chromosome-Specific Libraries: Detection of Trisomy 21 and Translocations of Chromosome 4," PNAS (USA), Vol. 85, Dec. 1988, pp. 9138-9142

Pinkel et al, "Cytogenetics Using Fluorescent Nucleic Acid Probes and Quantitative Microscopic Measurement" (UCRL 93269 Abstract) Analytical Cytology X Conference, Hilton Head Resort, Hilton Head Island, S.C., 11/17/85 - 11/22/85

Pinkel et al, "Rapid Quantitative Cytogenetic Analysis Using Fluorescently Labeled Nucleic Acid Probes", (UCRL 93553 Abstract), U.S. - Japan Joint Environmental Panel Conf., Research Triangle Park, N.C., 10/21/85 - 10/23/85

Pinkel et al, "Detection of Structural and Numerical Abnormalities in Metaphase Spreads and Interphase Nuclei Using In Situ Hybridization", Cancer Genet. and Cytogenet. (UCRL 101043 Abstract) 41:236 (October 1989)

Pinkel et al, "Detection of Translocations and Aneuploidy in Metaphase Spreads and Interphase Nuclei by In Situ Hybridization with Probes Which Stain Entire Human Chromosomes," (UCRL 101042 Abstract) 21st Oak Ridge Conference on Advanced Concepts in the Clinical Laboratory, 4/13/89 - 4/14/89

Rappold et al, "Sex Chromosome Positions in Human Interphase Nuclei as Studied by *in situ* Hybridization with Chromosome Specific DNA Probes," Human Genetics, Vol. 67, 1984, pp. 317-322

Roelofs et al, "Gene Amplification in Human Cells May Involve Interchromosomal Transposition and Persistence of the Original DNA Region," The New Biologist, Vol. 4, No. 1, (Jan. 1992), pp. 75-86

Scalenghe et al, "Microdissection and Cloning of DNA from a Specific Region of *Drosophila melanogaster* Polytene Chromosomes," Chromosoma (Berl.), Vol. 82, 1981, pp. 205-216

Schardin et al, "Specific Staining of Human Chromosomes in Chinese Hamster X Man Hybrid Cell Lines Demonstrates Interphase Chromosome Territories," Hum. Genet., Vol. 71, 1985, pp. 281-287

Schmeckpeper et al, "Partial Purification and Characterization of DNA from the Human X Chromosome," PNAS (USA), Vol. 76, No. 12, Dec. 1979, pp. 6525-6528

Sealey, et al, "Removal of Repeated Sequences from Hybridisation Probes," Nucleic Acid Research, Vol. 13, No. 6, 1985, pp. 1905-1922

Selypes et al, "A Noninvasive Method for Determination of the Sex and Karyotype of the Fetus from the Maternal Blood," Hum. Genet., Vol. 79, 1988, pp. 357-359

Smith et al, "Distinctive Chromosomal Structures Are Formed Very Early in the Amplification of CAD Genes in Syrian Hamster Cells," Cell, Vol. 63, (Dec. 21, 1990), pp. 1219-1227

Sparkes et al, "Regional Assignment of Genes for Human Esterase D and Retinoblastoma to Chromosome Band 13q14," Science, Vol. 208, May 30, 1988, pp. 1042-1044

Stewart et al, "Cloned DNA Probes Regionally Mapped to Human Chromosome 21 and Their Use in Determining the Origin of Nondisjunction," Nucleic Acids Research, Vol. 13, No. 11, 1985, pp. 4125-4132

Straume et al, "Chromosome Translocation of Low Radiation Doses Quantified Using Fluorescent DNA Probes", (UCRL 93837 Abstract), Radiation Research Society Meeting, Las Vegas, Nevada, 4/12/86 - 4/17/86

Szabo et al, "What's New With Hybridization *in situ*?", TIBS, Vol. 7, No. 11, December 1982, pp. 425-427

Thompson et al, Thompson & Thompson: Genetics in Medicine, 5th ed., W.B. Saunders Co., Philadelphia, PA, pages 38-39 (1991)

Trask et al, "The Proximity of DNA Sequences in Interphase Cell Nuclei Is Correlated to Genomic Distance and Permits Ordering of Cosmids Spanning 250 Kilobase Pairs," Genomics, Vol. 5, 1989, pp. 710-717

Trask et al, "Detection of DNA Sequences in Nuclei in Suspension by In Situ Hybridization and Dual Beam Flow Cytometry" (UCRL 93372 Abstract) - Analytical Cytology X Conference, Hilton Head Resort, Hilton Head Island, S.C., 11/17/85 - 11/22/85

Trask et al, "Early Dihydrofolate Reductase Gene Amplification Events in CHO Cells Usually Occur on the Same Chromosome Arm as the Original Locus," Genes & Development, Vol. 3, (1989), pp. 1913-1925

Trent et al, "Report of the Committee on Structural Chromosome Changes in Neoplasia," Cytogenet. Cell Genet., Vol. 51, 1989, pp. 533-562

Van Dilla et al, "Construction and Availability of Human Chromosome-Specific DNA Libraries From Flow Sorted Chromosomes: Status Report," Am. J. of Human Genetics, Vol. 37 (R Supplement) July 1985, p. A179

Information Disclosure Statement
Application Serial No. 08/477,316
Attorney's Docket No. 028723-060
Page 10

Wallace et al, "The Use of Synthetic Oligonucleotides as Hybridization Probes - II
Hybridization of Oligonucleotides of Mixed Sequence to Rabbit β Globin DNA," Nucleic
Acids Research, Vol. 9, No. 4, 1981, pp. 879-894

Weiss et al, "Organization and Evolution of the Class I Gene Family in the Major
Histocompatibility Complex of the C57BL/10 Mouse," Nature, Vol. 310, No. 23, Aug.
1984, pp. 650-655

Willard et al, "Isolation and Characterization of a Major Tandem Repeat Family from the
Human X Chromosome," Nucleic Acids Research, Vol. 11, No. 7, 1983, pp. 2017-2033

Windle et al, "A Central Role for Chromosome Breakage in Gene Amplification, Deletion
Formation, and Amplicon Integration," Genes & Development, Vol. 5, (1991), pp.
160-174

Yunis et al, "Localization of Sequences Specifying Messenger RNA to Light-Staining
G-Bands of Human Chromosomes," Chromosoma (Berl.), Vol. 61, 1977, pp. 335-344

The documents are being submitted within 3 months of the filing or entry of the
national stage of this application or before the first Office Action on the merits,
whichever is later, therefore no fee or certification is required under 37 C.F.R. § 1.97(b).

To assist the Examiner, the documents are listed on the attached form PTO-1449.
It is respectfully requested that an Examiner initialled copy of this form be returned to the
undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS

By:



Donna M. Meuth
Registration No. 36,607

P.O. Box 1404
Alexandria, VA 22313-1404
Phone: (703) 836-6620

Date: September 7, 1995